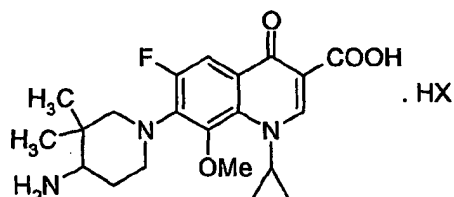


CLAIMS:

1. (Original) A polymorph of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride, R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride, S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride and racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate, R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate, S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate having the formula I and II respectively



Formula I HX = HCl
Formula II HX = CH₃SO₃H

wherein said polymorph is selected from the group comprising

- a) a racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-3 exhibiting the following X-ray diffraction pattern
(2 θ): 5.32 \pm 0.2°, 5.68 \pm 0.2°, 9.42 \pm 0.2°, 10.06 \pm 0.2°, 10.40 \pm 0.2°, 11.40 \pm 0.2°, 11.78 \pm 0.2°, 12.98 \pm 0.2°, 13.74 \pm 0.2°, 14.38 \pm 0.2°, 14.66 \pm 0.2°, 16.02 \pm 0.2°, 22.52 \pm 0.2°, 23.74 \pm 0.2°, 24.48 \pm 0.2°, 25.22 \pm 0.2°, 27.36 \pm 0.2°, 28.74 \pm 0.2°, 31.28 \pm 0.2°, 31.72 \pm 0.2°.

- b) a R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-3 exhibiting the following X-ray diffraction pattern
(2 θ): $5.34 \pm 0.2^\circ$, $5.70 \pm 0.2^\circ$, $9.46 \pm 0.2^\circ$, $10.08 \pm 0.2^\circ$, $10.44 \pm 0.2^\circ$, $11.42 \pm 0.2^\circ$, $11.82 \pm 0.2^\circ$, $12.86 \pm 0.2^\circ$, $13.62 \pm 0.2^\circ$, $14.26 \pm 0.2^\circ$, $14.72 \pm 0.2^\circ$, $16.08 \pm 0.2^\circ$, $22.16 \pm 0.2^\circ$, $23.68 \pm 0.2^\circ$, $24.18 \pm 0.2^\circ$, $24.86 \pm 0.2^\circ$, $25.98 \pm 0.2^\circ$, $27.04 \pm 0.2^\circ$, $28.84 \pm 0.2^\circ$, $31.56 \pm 0.2^\circ$, $31.84 \pm 0.2^\circ$.
- c) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-3 exhibiting the following X-ray diffraction pattern
(2 θ): $7.04 \pm 0.2^\circ$, $7.70 \pm 0.2^\circ$, $8.06 \pm 0.2^\circ$, $12.34 \pm 0.2^\circ$, $12.78 \pm 0.2^\circ$, $13.64 \pm 0.2^\circ$, $15.40 \pm 0.2^\circ$, $16.14 \pm 0.2^\circ$, $18.62 \pm 0.2^\circ$, $19.40 \pm 0.2^\circ$, $20.64 \pm 0.2^\circ$, $21.84 \pm 0.2^\circ$, $23.22 \pm 0.2^\circ$, $26.80 \pm 0.2^\circ$, $27.88 \pm 0.2^\circ$, $29.86 \pm 0.2^\circ$, $32.30 \pm 0.2^\circ$, $33.36 \pm 0.2^\circ$, $37.02 \pm 0.2^\circ$, $39.24 \pm 0.2^\circ$.
- d) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-4 exhibiting the following X-ray diffraction pattern
(2 θ): $5.34 \pm 0.2^\circ$, $5.68 \pm 0.2^\circ$, $9.48 \pm 0.2^\circ$, $10.08 \pm 0.2^\circ$, $10.44 \pm 0.2^\circ$, $11.42 \pm 0.2^\circ$, $11.84 \pm 0.2^\circ$, $12.86 \pm 0.2^\circ$, $13.62 \pm 0.2^\circ$, $14.24 \pm 0.2^\circ$, $14.74 \pm 0.2^\circ$, $16.08 \pm 0.2^\circ$, $22.16 \pm 0.2^\circ$, $24.14 \pm 0.2^\circ$, $24.82 \pm 0.2^\circ$, $25.94 \pm 0.2^\circ$, $27.02 \pm 0.2^\circ$, $28.84 \pm 0.2^\circ$, $31.82 \pm 0.2^\circ$.
- e) a racemic-(\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-1 exhibiting the following X-ray diffraction pattern
(2 θ): $5.80 \pm 0.2^\circ$, $8.08 \pm 0.2^\circ$, $9.08 \pm 0.2^\circ$, $12.92 \pm 0.2^\circ$, $14.70 \pm 0.2^\circ$, $16.48 \pm 0.2^\circ$, $17.40 \pm 0.2^\circ$, $18.36 \pm 0.2^\circ$, $18.74 \pm 0.2^\circ$, $19.60 \pm 0.2^\circ$, $20.44 \pm 0.2^\circ$, $20.94 \pm 0.2^\circ$, $21.50 \pm 0.2^\circ$, $22.80 \pm 0.2^\circ$, $23.28 \pm 0.2^\circ$, $23.84 \pm 0.2^\circ$, $24.36 \pm 0.2^\circ$, $25.50 \pm 0.2^\circ$, $26.00 \pm 0.2^\circ$, $26.78 \pm 0.2^\circ$, $27.24 \pm 0.2^\circ$, $29.22 \pm 0.2^\circ$, $30.66 \pm 0.2^\circ$, $37.58 \pm 0.2^\circ$.

- f) a R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-1 exhibiting the following X-ray diffraction pattern
(2 θ): $5.74 \pm 0.2^\circ$, $8.02 \pm 0.2^\circ$, $9.02 \pm 0.2^\circ$, $12.84 \pm 0.2^\circ$, $14.74 \pm 0.2^\circ$, $16.46 \pm 0.2^\circ$, $17.32 \pm 0.2^\circ$, $18.38 \pm 0.2^\circ$, $19.58 \pm 0.2^\circ$, $20.38 \pm 0.2^\circ$, $20.92 \pm 0.2^\circ$, $21.48 \pm 0.2^\circ$, $22.80 \pm 0.2^\circ$, $23.80 \pm 0.2^\circ$, $24.28 \pm 0.2^\circ$, $25.62 \pm 0.2^\circ$, $26.88 \pm 0.2^\circ$, $27.32 \pm 0.2^\circ$, $28.20 \pm 0.2^\circ$, $29.16 \pm 0.2^\circ$, $30.68 \pm 0.2^\circ$.
- g) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-1 exhibiting the following X-ray diffraction pattern
X-ray powder diffraction (2 θ): $8.02 \pm 0.2^\circ$, $12.84 \pm 0.2^\circ$, $14.70 \pm 0.2^\circ$, $16.44 \pm 0.2^\circ$, $17.30 \pm 0.2^\circ$, $19.56 \pm 0.2^\circ$, $20.90 \pm 0.2^\circ$, $21.46 \pm 0.2^\circ$, $23.76 \pm 0.2^\circ$, $25.56 \pm 0.2^\circ$, $27.30 \pm 0.2^\circ$, $30.66 \pm 0.2^\circ$, $37.46 \pm 0.2^\circ$.
- h) a racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-2 exhibiting the following X-ray diffraction pattern
(2 θ): $9.40 \pm 0.2^\circ$, 9.94 , $10.74 \pm 0.2^\circ$, $12.32 \pm 0.2^\circ$, $12.98 \pm 0.2^\circ$, $14.02 \pm 0.2^\circ$, $15.72 \pm 0.2^\circ$, $16.92 \pm 0.2^\circ$, $18.84 \pm 0.2^\circ$, $19.38 \pm 0.2^\circ$, $20.52 \pm 0.2^\circ$, $21.20 \pm 0.2^\circ$, 22.80 , $22.96 \pm 0.2^\circ$, $24.64 \pm 0.2^\circ$, $25.54 \pm 0.2^\circ$, $28.38 \pm 0.2^\circ$, $29.92 \pm 0.2^\circ$, $30.72 \pm 0.2^\circ$, 35.92 , $37.88 \pm 0.2^\circ$.
- i) a R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-2 exhibiting the following X-ray diffraction pattern
(2 θ): $8.04 \pm 0.2^\circ$, $9.36 \pm 0.2^\circ$, $10.06 \pm 0.2^\circ$, $10.84 \pm 0.2^\circ$, $12.24 \pm 0.2^\circ$, $12.88 \pm 0.2^\circ$, $13.94 \pm 0.2^\circ$, $15.26 \pm 0.2^\circ$, $15.76 \pm 0.2^\circ$, $16.82 \pm 0.2^\circ$, $17.16 \pm 0.2^\circ$, $18.78 \pm 0.2^\circ$, $19.62 \pm 0.2^\circ$, $20.42 \pm 0.2^\circ$, $21.22 \pm 0.2^\circ$, $22.30 \pm 0.2^\circ$, $23.16 \pm 0.2^\circ$, $24.26 \pm 0.2^\circ$, $24.62 \pm 0.2^\circ$, $25.54 \pm 0.2^\circ$, $28.38 \pm 0.2^\circ$, $30.00 \pm 0.2^\circ$, $30.84 \pm 0.2^\circ$, $38.18 \pm 0.2^\circ$.

- j) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-2 exhibiting the following X-ray diffraction pattern
(2 θ): 9.38 \pm 0.2°, 10.04 \pm 0.2°, 12.28 \pm 0.2°, 12.94 \pm 0.2°, 13.98 \pm 0.2°, 15.78 \pm 0.2°, 16.86 \pm 0.2°, 18.80 \pm 0.2°, 19.62 \pm 0.2°, 21.24 \pm 0.2°, 22.32 \pm 0.2°, 23.18 \pm 0.2°, 24.64 \pm 0.2°, 25.56 \pm 0.2°, 28.44 \pm 0.2°, 30.02 \pm 0.2°, 30.90 \pm 0.2°, 39.74 \pm 0.2°.

2. (Original).The compound according to claim 1 corresponding to polymorph A-3 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
3. (Original).The compound according to claim 1 corresponding to polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
4. (Original).The compound according to claim 1 corresponding to polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
5. (Original).The compound according to claim 1 corresponding to polymorph A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
6. (Original).The compound according to claim 1 corresponding to polymorph B-1 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
7. (Original).The compound according to claim 1 corresponding to polymorph B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
8. (Original).The compound according to claim 1 corresponding to polymorph B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.

- 9.(Original). The compound according to claim 1 corresponding to polymorph B-2 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
- 10.(Original). The compound according to claim 1 corresponding to polymorph B-2 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
- 11.(Original). The compound according to claim 1 corresponding to polymorph B-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
- 12.(Original). A process for preparing polymorph A-3 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern
- (2 θ): $5.32 \pm 0.2^\circ$, $5.68 \pm 0.2^\circ$, $9.42 \pm 0.2^\circ$, $10.06 \pm 0.2^\circ$, $10.40 \pm 0.2^\circ$, $11.40 \pm 0.2^\circ$, $11.78 \pm 0.2^\circ$, $12.98 \pm 0.2^\circ$, $13.74 \pm 0.2^\circ$, $14.38 \pm 0.2^\circ$, $14.66 \pm 0.2^\circ$, $16.02 \pm 0.2^\circ$, $22.52 \pm 0.2^\circ$, $23.74 \pm 0.2^\circ$, $24.48 \pm 0.2^\circ$, $25.22 \pm 0.2^\circ$, $27.36 \pm 0.2^\circ$, $28.74 \pm 0.2^\circ$, $31.28 \pm 0.2^\circ$, $31.72 \pm 0.2^\circ$.
- which process comprises the steps of
- drying polymorphic A-1 form of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C , optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and
 - recovering the polymorphic form A-3 as a crystalline solid.
- 13.(Original). A process for preparing polymorph A-3 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride, exhibiting the X-ray diffraction pattern
- (2 θ): $5.32 \pm 0.2^\circ$, $5.68 \pm 0.2^\circ$, $9.42 \pm 0.2^\circ$, $10.06 \pm 0.2^\circ$, $10.40 \pm 0.2^\circ$, $11.40 \pm 0.2^\circ$, $11.78 \pm 0.2^\circ$, $12.98 \pm 0.2^\circ$, $13.74 \pm 0.2^\circ$, $14.38 \pm 0.2^\circ$, $14.66 \pm 0.2^\circ$, $16.02 \pm 0.2^\circ$, $22.52 \pm 0.2^\circ$, $23.74 \pm 0.2^\circ$, $24.48 \pm 0.2^\circ$, $25.22 \pm 0.2^\circ$, $27.36 \pm 0.2^\circ$, $28.74 \pm 0.2^\circ$, $31.28 \pm 0.2^\circ$, $31.72 \pm 0.2^\circ$.

which process comprises the steps of :

- a) drying polymorphic A-2 form of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C, optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and
- b) recovering the polymorphic form A-3 as a crystalline solid.

14.(Original). A process for preparing polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern

(2 θ): $5.34 \pm 0.2^\circ$, $5.70 \pm 0.2^\circ$, $9.46 \pm 0.2^\circ$, $10.08 \pm 0.2^\circ$, $10.44 \pm 0.2^\circ$, $11.42 \pm 0.2^\circ$, $11.82 \pm 0.2^\circ$, $12.86 \pm 0.2^\circ$, $13.62 \pm 0.2^\circ$, $14.26 \pm 0.2^\circ$, $14.72 \pm 0.2^\circ$, $16.08 \pm 0.2^\circ$, $22.16 \pm 0.2^\circ$, $23.68 \pm 0.2^\circ$, $24.18 \pm 0.2^\circ$, $24.86 \pm 0.2^\circ$, $25.98 \pm 0.2^\circ$, $27.04 \pm 0.2^\circ$, $28.84 \pm 0.2^\circ$, $31.56 \pm 0.2^\circ$, $31.84 \pm 0.2^\circ$.

which process comprises the steps of

- a. drying polymorphic A-1 form of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C, optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and
- b. recovering the polymorphic form A-3 as a crystalline solid.

15.(Original). A process for preparing polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern

(2 θ): $5.34 \pm 0.2^\circ$, $5.70 \pm 0.2^\circ$, $9.46 \pm 0.2^\circ$, $10.08 \pm 0.2^\circ$, $10.44 \pm 0.2^\circ$, $11.42 \pm 0.2^\circ$, $11.82 \pm 0.2^\circ$, $12.86 \pm 0.2^\circ$, $13.62 \pm 0.2^\circ$, $14.26 \pm 0.2^\circ$, $14.72 \pm 0.2^\circ$, $16.08 \pm 0.2^\circ$, $22.16 \pm 0.2^\circ$, $23.68 \pm 0.2^\circ$, $24.18 \pm 0.2^\circ$, $24.86 \pm 0.2^\circ$, $25.98 \pm 0.2^\circ$, $27.04 \pm 0.2^\circ$, $28.84 \pm 0.2^\circ$, $31.56 \pm 0.2^\circ$, $31.84 \pm 0.2^\circ$.

which process comprises the steps of

- a) drying polymorphic A-2 form of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C,

optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and

b) recovering the polymorphic form A-3 as a crystalline solid.

- 16.(Original). A process for preparing polymorph A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride, exhibiting the X-ray diffraction pattern
(2 θ): $5.34 \pm 0.2^\circ$, $5.68 \pm 0.2^\circ$, $9.48 \pm 0.2^\circ$, $10.08 \pm 0.2^\circ$, $10.44 \pm 0.2^\circ$, $11.42 \pm 0.2^\circ$, $11.84 \pm 0.2^\circ$, $12.86 \pm 0.2^\circ$, $13.62 \pm 0.2^\circ$, $14.24 \pm 0.2^\circ$, $14.74 \pm 0.2^\circ$, $16.08 \pm 0.2^\circ$, $22.16 \pm 0.2^\circ$, $24.14 \pm 0.2^\circ$, $24.82 \pm 0.2^\circ$, $25.94 \pm 0.2^\circ$, $27.02 \pm 0.2^\circ$, $28.84 \pm 0.2^\circ$, $31.82 \pm 0.2^\circ$.
which process comprises the steps of:

- a) drying polymorphic A-3 form of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C , optionally under reduced pressure sufficient to effect transformation to polymorphic form A-4; and
- b) recovering the polymorphic form A-4 as a crystalline solid.

- 17.(Original). A process for preparing polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern
(2 θ): $7.04 \pm 0.2^\circ$, $7.70 \pm 0.2^\circ$, $8.06 \pm 0.2^\circ$, $12.34 \pm 0.2^\circ$, $12.78 \pm 0.2^\circ$, $13.64 \pm 0.2^\circ$, $15.40 \pm 0.2^\circ$, $16.14 \pm 0.2^\circ$, $18.62 \pm 0.2^\circ$, $19.40 \pm 0.2^\circ$, $20.64 \pm 0.2^\circ$, $21.84 \pm 0.2^\circ$, $23.22 \pm 0.2^\circ$, $26.80 \pm 0.2^\circ$, $27.88 \pm 0.2^\circ$, $29.86 \pm 0.2^\circ$, $32.30 \pm 0.2^\circ$, $33.36 \pm 0.2^\circ$, $37.02 \pm 0.2^\circ$, $39.24 \pm 0.2^\circ$.
which process comprises the steps of

- a) suspending or dissolving polymorphic form A-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride in water, if necessary by heating;
- b) stirring the mixture to form a suspension or a solution followed by adding a water-miscible organic solvent;
- c) recovering the polymorphic form A-3 as a crystal upon cooling the solution and filtrating; and
- d) drying resultant crystals to constant weight to provide the polymorph A-3.

- 18.(Original). A process for preparing polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern
(2 θ): 7.04 \pm 0.2°, 7.70 \pm 0.2°, 8.06 \pm 0.2°, 12.34 \pm 0.2°, 12.78 \pm 0.2°, 13.64 \pm 0.2°, 15.40 \pm 0.2°, 16.14 \pm 0.2°, 18.62 \pm 0.2°, 19.40 \pm 0.2°, 20.64 \pm 0.2°, 21.84 \pm 0.2°, 23.22 \pm 0.2°, 26.80 \pm 0.2°, 27.88 \pm 0.2°, 29.86 \pm 0.2°, 32.30 \pm 0.2°, 33.36 \pm 0.2°, 37.02 \pm 0.2°, 39.24 \pm 0.2°.
which process comprises the steps of:
- a) suspending or dissolving polymorphic form A-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride in water, if necessary by heating;
 - b) adding a water-miscible organic solvent and stirring resulting mixture for a sufficient period of time to effect the transformation completely to polymorphic form A-3;
 - c) recovering the polymorphic form A-3 as a crystal upon cooling the solution and filtering; and
 - d) drying the resultant crystals to a constant weight to yield the product A-3..
- 19.(Original). A process for preparing polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride, from said polymorphs A-1 or A-2 or A-4 which process comprises
- a) suspending or dissolving polymorphic form A-1 or A-2 or A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride in water, if necessary by heating;
 - b) stirring the mixture at that temperature to form a suspension or a solution followed by adding a water-miscible organic solvent;
 - c) recovering the polymorphic form A-3 as a crystal upon cooling the solution and filtrating;
 - d) drying the resultant crystals to a constant weight to yield the product of the invention.
- 20.(Original). A process for preparing polymorph B-1 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- a) suspending or dissolving racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid in a suitable organic solvent to form a suspension/solution;
- b) heating the suspension/solution and adding methane sulfonic acid at the elevated temperature;
- c) heating the reaction mixture at elevated temperature sufficient to effect transformation to the mesylate polymorphic form B-1;
- d) recovering the polymorphic form B-1 as a crystal upon cooling the solution and filtering;
- e) drying crystals to a constant weight to yield the polymorph B-1 of the invention.

21.(Original). A process for preparing polymorph B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- a) suspending or dissolving R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid in a suitable organic solvent to form a suspension/solution;
- b) heating the suspension/solution and adding methane sulfonic acid at the elevated temperature;
- c) heating the reaction mixture at elevated temperature sufficient to effect transformation to the mesylate polymorphic form B-1;
- d) recovering the polymorphic form B-1 as a crystal upon cooling the solution and filtering;
- e) drying crystals to a constant weight to yield the polymorph B-1 of the invention.

22.(Original). A process for preparing polymorph B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- a) suspending or dissolving (-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid in a suitable organic solvent to form a suspension/solution;
- b) heating the suspension/solution and adding methane sulfonic acid at the elevated temperature;

- c) heating the reaction mixture at elevated temperature sufficient to effect transformation to the mesylate polymorphic form B-1;
- d) recovering the polymorphic form B-1 as a crystal upon cooling the solution and filtering;
- e) drying crystals to a constant weight to yield the polymorph B-1 of the invention.

23.(Original). A process for preparing polymorph B-2 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- a) dissolving crystalline polymorphic form B-1 of racemic (\pm)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate in water by heating to form a solution;
- b) cooling the solution and adding an aqueous-miscible organic solvent;
- c) allowing the reaction mixture to stand for a sufficient time to effect transformation to polymorphic form B-2,
- d) recovering the polymorphic form B-2 as a crystal upon cooling and filtering;
- e) drying resultant crystals to a constant weight to yield the polymorph B-2 of the invention.

24.(Original). A process for preparing polymorph B-2 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- a) dissolving crystalline polymorphic form B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate in water by heating to form a solution;
- b) cooling the solution and adding an aqueous-miscible organic solvent;
- c) allowing the reaction mixture to stand for a sufficient time to effect transformation to polymorphic form B-2,
- d) recovering the polymorphic form B-2 as a crystal upon cooling and filtering;
- e) drying resultant crystals to a constant weight to yield the polymorph B-2 of the invention.

- f) A process for preparing polymorph B-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises
- g) dissolving crystalline polymorphic form B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate in water by heating to form a solution;
- h) cooling the solution and adding an aqueous-miscible organic solvent;
- i) allowing the reaction mixture to stand for a sufficient time to effect transformation to polymorphic form B-2,
- j) recovering the polymorphic form B-2 as a crystal upon cooling and filtering;
- k) drying resultant crystals to a constant weight to yield the polymorph B-2 of the invention.

Claims 25-56. (CANCELLED).